510(k) Summary of Safety and Effectiveness in accordance with 21 CFR Part 807, Subpart E, Section 807.92.

JUN 11 2014

21 CFR 807.92, Subsection a

1. Submitter's Information

Hitachi Aloka Medical, Ltd.
10 Fairfield Boulevard
Wallingford, CT 06492-5903

Contact:
Angela Van Arsdale
RA/QA Manager

Telephone: (203) 269-5088 Ext: 346
Fax Number: (203) 269-6075

Date Prepared: April 1, 2014

2. Device / Common / Classification Name / Classification / Product Code:

Device Proprietary Name – UST-5310 and UST-5311
Common name - Diagnostic Ultrasound Transducer
Classification name - Diagnostic Ultrasonic Transducer
Classification: Class II
Product Code: 90-ITX 892.1570 Diagnostic Ultrasonic Transducer

3. Legally Marketed Predicate Device(s):

UST-533 Intraoperative Ultrasound Transducer [K122537]
UST-534 Intraoperative Ultrasound Transducer [K122537]
UST-536 Intraoperative Ultrasound Transducer [K122537]

4. Device Description:

Linear Array transducer

5. Indication for Use:

Sterile single-use Intra-Operative Linear transducer for use in conjunction with ProSound Alpha 6 [K093488]

6. Comparison to predicate device:

The Hitachi Aloka Medical, Ltd. UST-5310 and UST-5311 Intraoperative transducers are technically comparable and substantially equivalent to the currently marketed UST-533, UST-534 & UST-536 Intraoperative transducers. The subject and predicate systems are track 3 systems that incorporate the same fundamental and scientific technologies. The follows compares the subject and predicate devices:

Subject devices:	Predicate devices:
Single-use sterile device – sterilized via EtO	Reusable device – Sterilized via EtO
New material: Ethylene Vinyl Acetate	All materials previously cleared by FDA
Intraoperative linear array	Intraoperative linear array
Modes of operation: B, M, PWD, CD, PowerFlow and Combination of each operating mode	Modes of operation: B, M, PWD, CD, PowerFlow and Combination of each operating mode

21 CFR Part 807.92, Section b

1. Non-clinical Testing

No new hazards were identified with the addition of the added indications and software features. The subject device and its transducers have been evaluated for acoustic output, biocompatibility, cleaning & disinfection effectiveness, electromagnetic compatibility, as well as electrical and mechanical safety, and have been found to conform to applicable medical device safety standards.

2. Clinical testing:

None required

3. Conclusions:

The Hitachi Aloka Medical, Ltd. Sterile Transducer is substantially equivalent in safety and effectiveness to the predicate device:

- The subject and predicate device(s) are both indicated for diagnostic ultrasound imaging.
- The subject and predicate device(s) have the same gray scale and Doppler capabilities.
- The subject and predicate device(s) have the same essential technology for imaging, Doppler functions, and signal processing.
- The subject and predicate device(s) have acoustic level below the Track 3 FDA limits.
- The subject and predicate device(s) are manufactured in accordance to FDA 21 CFR 820 Quality System Regulations.
- The subject and predicate device(s) are designed and manufactured to the same electrical and physical safety standards.
- The subject and predicate device(s) are manufactured with materials that have been tested in accordance to ISO 10993-1; all biocompatibility testing has been conducted in accordance to each component material characterization, type of body contact, and duration contact risk profile.
- The subject and predicate device(s) are designed to be sterilized via EtO, the only difference is that the subject device is supplied sterile and the predicate is supplied non-sterile with instructions for cleaning, disinfection, and sterilization in the transducer manuals.

END OF SUMMARY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 11, 2014

Hitachi Aloka Medical, Ltd.
% Ms. Angela Van Arsdale
Regulatory Affairs/Quality Assurance Manager
10 Fairfield Blvd.
WALLINGFORD CT 06492

Re: K140854
Trade/Device Name: UST-5310 and UST-5311 Intra-operative Ultrasound Transducers
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: May 30, 2014
Received: June 2, 2014

Dear Ms. Van Arsdale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140854

Device Name
UST-5310 / UST-5311

Indications for Use *(Describe)*
The Hitachi Aloka Medical, Ltd. UST-5310 / UST-5311 transducers for use with the PROSOUND ALPHA6 Diagnostic Ultrasound scanner are intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation during Intra-operative and Intra-operative (neurosurgery) procedures.

The device is not indicated for Ophthalmic applications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi ProSound Alpha 6 K093488
Transducer: UST-5310
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Specify)	Other** (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*	E	E	E		E	E	E
	Intra-operative (Neurosurgery)	E	E	E		E	E	E
	Laparoscopic**							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac – Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication, P = previously cleared by FDA; E = added under Appendix 1 - Specifications
Combination of each operating mode includes:
*1 Combination of each operating mode- B/M, B/PWD, M/CD, B/CD/PWD, B/CWD, B/CD/CWD **2 Includes: Mflow, B/Bflow, Power flow.

Intra-operative (Specify)* - (liver, pancreas, gall bladder..)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi ProSound Alpha 6 K093488
Transducer: UST-5311
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Specify)	Other** (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*	E	E	E		E	E	E
	Intra-operative (Neurosurgery)	E	E	E		E	E	E
	Laparoscopic**							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac – Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA; E = added under Appendix I - Specifications
Combination of each operating mode includes:

*1 Combination of each operating mode- B/M, B/PWD, M/CD, B/CD/PWD, B/CWD, B/CD/CWD **2 Includes: Mflow, B/Bflow, Power flow.

Intra-operative (Specify)* - (liver, pancreas, gall bladder..)

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